Memo. 322/B.C.G. (Revised 1964)

MINISTRY OF HEALTH

SCOTTISH HOME AND HEALTH DEPARTMENT

B.C.G. VACCINATION

MEDICAL MEMORANDUM

This memorandum replaces Memo. 332/B.C.G. (Revised 1958) which is now cancelled. Particular reference is made to (1) the technique of tuberculin testing; (2) the type of vaccine; (3) the stability of the vaccine; (4) the distribution of the vaccine; (5) the groups to be vaccinated; (6) technique of vaccination; (7) details concerning the vaccination programme; (8) complications; and (9) record keeping.

(1) Technique of Tuberculin Testing

(*a*) *The Tuberculin.* In order to procure uniformity of results it is desirable to use the official supply of preparations of a purified protein derivative (P.P.D.) prepared by the Ministry of Agriculture, Fisheries and Food which are obtainable free of charge by application on Form B.C.G. 7 (Revised) to the appropriate supply department. In England and Wales applications should be sent to the Ministry of Health, Supply Division S2B, 14, Russell Square, London, W.C.1. and in Scotland to the Infusion Fluids Laboratory, 112, Ingram Street, Glasgow, C.1. Deliveries will be made direct by the Ministry's contractor.

The P.P.D. preparations suitable for Mantoux Test are those dilutions that provide the equivalent of 1 Tuberculin Unit in a dose of 0·1 ml or the equivalent of 10 Tuberculin Units in a dose of 0·1 ml. (These dilutions are sometimes referred to as the 1 in 10,000 and 1 in 1,000 dilutions). Diluted tuberculin preparations have a relatively short life and neither of the above strengths of P.P.D. should be used later than three weeks from the date of preparation (clearly marked on the back of each carton of ampoules).

There is a special dilution of P.P.D. issued for the 'multiple puncture' test. This is supplied in bottles of 1 ml. in cartons labelled "For Multiple Puncture Test Only". This P.P.D. contains the equivalent of 100,000 units of Old Tuberculin in 1 ml. It is sometimes referred to as "2mg/ml". A 1 ml. bottle of this material should suffice for 50 to 100 tests. This strength of P.P.D. is a relatively stable product with a life of one year.

Once a container of any P.P.D. preparation is opened the contents should be used without delay and at the end of a session any surplus remaining must be discarded. *All P.P.D. tuberculin, irrespective of strength, should be stored in the dark at* 2° *to* 4°*C.*

(*b*) *The Test*

(i) *The Intradermal Test* (*Mantoux Test*)

In carrying out the test an area of skin, usually over the upper third of the flexor surface of the forearm, is cleaned with spirit and 0·1 ml.

of tuberculin is injected *intradermally* so that a wheal is produced about 5 mm. in diameter. Unless there is reason to expect a high level of sensitivity, a single prevaccination test using 0·1 ml. of the 1/1,000 dilution i.e. 10 Tuberculin Units (T.U.) should be made. A positive result consists of a raised area having induration of not less than 6 mm. in diameter. The result should be read at the end of 72 hours. In some cases, however, the reaction is delayed for 96 hours.

(ii) *The Multiple Puncture Test* (*Heaf Test*)

The 'multiple puncture' test gives results variously estimated as the equivalent of the intradermal test using 50 or more T.U.s. For this test the Heaf Multiple Puncture Apparatus is used. A 2 mm. depth of puncture is recommended for all ages over two years; under that age the 1 mm. puncture is sufficient.

Sterilisation of multiple puncture apparatus is best done by merely moistening the end plate on the surface of methylated spirit in a Petri dish and then passing it through a flame to ignite the retained spirit which is allowed to burn off. Bacteriological investigation has shown that this method is effective for the de Hamel type head,* but care must be taken not to allow the needles to become over-heated while excess spirit burns off.

The P.P.D. tuberculin of special strength is applied to a cleaned dry area of the forearm with a sterile glass rod, pipette or eye dropper which should not be allowed to come into contact with the skin. The tuberculin is smoothed over by the end plate of the apparatus, which is then pressed firmly at right angles to the skin surface over the area and the needles released. Excess tuberculin is then removed.

In this test a positive result should only be recorded when there is palpable induration around at least four puncture points. The results may be read any time from four to seven days after puncture.

In appropriate circumstances, nurses or health visitors specially trained in the techniques involved, and working under the supervision of an experienced doctor, may be employed to perform the tests, read and record the results.

(iii) *The Tine Test*

This is a recently introduced proprietary test preparation which uses Old Tuberculin dried on to a set of needles held in a plastic base.

The skin is prepared as in the other tests, and the Tine Test Unit is removed from the base container. The patient's arm is cleaned and then gripped so as to stretch the skin of the forearm and the tines are applied firmly, held for at least 5 seconds and then withdrawn.

The reaction should be read at four to seven days, and the test is regarded as positive when one or more papules are palpable.

(c) *Positive Reactors*

It is recommended that those with severe reactions to a tuberculin test should be referred for further investigation and supervision. A severe reaction may be defined as over 15 mm. induration after a Mantoux Test of 10 T.U. or less, or a grade 3 or 4 reaction to the Heaf Test.

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*The de Hamel head is a modification in which the end plate is separated from the body of the gun by two metal pieces. This ensures that the needles are not withdrawn into the body of the gun where they might not be adequately heated during flaming.

(d) *Notification*

The medical practitioner first diagnosing tuberculosis, respiratory or non-respiratory, is required by Regulation 5 of the Public Health (Tuberculosis) Regulations 1952 to notify the case to the medical officer of health of the district concerned.

(2) Type of Vaccine

Laboratory and field investigations have shown that freeze-dried vaccine prepared in this country gives good tuberculin conversion rates and causes very few complications. This vaccine is supplied free of charge by the Ministry of Health and the Scottish Home and Health Department.

(3) Stability of the Vaccine

Freeze-dried B.C.G. Vaccine should be stored in a refrigerator at 2° to 4°C and should not be exposed to direct sunlight during a vaccination session. Material so stored may be used up to 12 months from the date of *manufacture*, but the expiry date printed on the container should in all cases be regarded as the date by which the vaccine is to be used.

Any surplus material left in open ampoules at the end of a session should be discarded.

(4) Distribution of Vaccine

B.C.G. vaccine is issued only to chest physicians, paediatricians, medical officers in charge of hospital staff, and Medical Officers of Health of local health authorities, any of whom may depute the administration of the vaccine to physicians working within the approved vaccination schemes.

Supplies should be requisitioned on Form B.C.G. 1 (a) for hospital staff and for persons who have been in contact with tuberculosis and (England and Wales only) on Form B.C.G. 1 (SC) (a) for schoolchildren.

The exact amount required should be clearly specified. The forms should be sent to Supply Division, S2B at the Ministry of Health, 14, Russell Square, London, W.C.1. four weeks if possible—in any case not less than two weeks—before the vaccine is needed for use. In Scotland applications should be sent to the Infusion Fluids Laboratory, 112, Ingram Street, Glasgow, C.1. Deliveries of the vaccine will be made by the manufacturers.

(5) Groups to be Vaccinated

(*a*) The opportunity is taken to make it clear that the group of hospital workers eligible for tuberculin testing and, if necessary, vaccination includes not only medical students and nurses but any others who are considered to be at special risk because of the likelihood of contact with patients or their fomites.

Contacts of known cases suffering from active tuberculosis and children and students of thirteen years and over should similarly be tested and, if need be, vaccinated. Schoolchildren aged 10 years or more may also be vaccinated if in the view of a local health authority this appears to be justified. It may be appropriate to offer vaccination to those of local authority public health staff who may be in contact with cases of tuberculosis.

It is desirable in new-born infants who are contacts to wait until the child begins to gain weight before vaccinating with B.C.G. In the case of infants pre-vaccination testing can be omitted.

(*b*) Hospital authorities should be responsible for the vaccination of hospital staff and for any patients who qualify for vaccination and local health authorities for all others.

(*c*) The following conditions contra-indicate vaccination:—

- (i) A positive reaction to the tuberculin test;
- (ii) Vaccination against smallpox, poliomyelitis or yellow fever during the previous four weeks;
- (iii) Pyrexia, septic dermatitis, irritant skin lesions.

(6) Technique of Vaccination

Full instructions for reconstitution of freeze-dried vaccine are given in the leaflet supplied with each ampoule of freeze-dried vaccine.

The site of inoculation is usually in the area over the insertion of the left deltoid muscle but, if desirable, the antero-lateral surface of the thigh can be used, except in infants.

The skin is cleaned with surgical spirit and the vaccine is drawn up from the ampoule into a standard quality sterile glass tuberculin syringe with a sterile luer needle, preferably 25 gauge, $\frac{1}{4}$" or $\frac{3}{8}$", specially reserved for the purpose. 0·1 ml. of the vaccine is then injected *intradermally* without loss due to leakage from the needle track. A satisfactory vaccination should produce a white wheal 5 mm. in diameter; no dressing is required.

It is of the greatest importance that tuberculin testing and vaccination techniques are kept at a high standard and that each procedure is performed correctly. Faulty technique is one of the most frequent causes of post-vaccination complications. In order to ensure that they are reduced to a minimum it is necessary for vaccinators to be acquainted with the possible variations associated with the reaction to tuberculin injection and also to be skilled in carrying out intradermal injections correctly.

(7) Additional points in the Vaccination Programme

(*a*) It is advisable to allow an interval of at least four weeks between B.C.G. vaccination and any other vaccination procedure.

(*b*) Segregation is advisable when there is reason to believe that the person to be vaccinated will be exposed to abnormal risk of infection by the tubercle bacillus during six weeks prior to and following the vaccination. It is, however, better to vaccinate without segregation than not to vaccinate at all.

(*c*) In infants a full adult dose of vaccine is liable to give rise to regional adenitis, and so half the dose normal for older children is recommended, although the allergy produced may not be so long lasting.

(*d*) With the present vaccine there is a high conversion rate and it is considered that the immediate post-vaccination test is necessary only in those at particular risk, e.g. contacts, so that this test can be dispensed with in the routine vaccination of schoolchildren and students. The normal time to do the post-vaccination test is ten to twelve weeks after vaccination.

(8) Complications

Normally a local reaction develops at the site of the vaccination in from two to six weeks. It begins as a small papule which slowly increases in size for two to three weeks and may develop into a shallow ulcer up to 10 mm. in diameter. If this discharges a dry dressing may have to be applied. The lesion slowly subsides after about two months, and eventually heals leaving only a small scar.

Complications following B.C.G. vaccination are rare and mostly consist of adenitis with or without suppuration and perforation. A minor degree of adenitis is common in the weeks following vaccination and should not be regarded as a complication. Very rarely a lupoid type of local lesion has been reported. Still more rarely a very few cases characterised by widespread dissemination of the injected organism have been reported in Europe during the past ten years. It is important that all complications are noted and a full record kept of their development and healing. It is desirable to make every effort to recover the causative organism from any lesion constituting a serious complication and to have it identified. This can be arranged at any laboratory of the Public Health Laboratory Service.

All persons with a serious complication should be referred to the chest physician. The family doctor of the patient should always be informed when a complication following vaccination occurs, and his consent obtained if treatment at a clinic is suggested.

The development of active tuberculosis in vaccinated persons is of the greatest interest. It is therefore important that the Medical Officer of Health should encourage doctors to inform him whether cases of tuberculosis which they notify have previously been given B.C.G. The Medical Officer of Health should usually be able to check from his own records whether a notified case has been vaccinated.

(9) Record Keeping

A Tuberculin Test and B.C.G. Vaccination Record Card should be completed for every person vaccinated under local health authority arrangements and retained by the Medical Officer of Health as it is important that individual records should be readily available to show the B.C.G. vaccination state of an individual and whether he was known to be tuberculin positive.

It may be of importance to know whether a patient with some lung condition has previously received B.C.G. vaccination or was known to be tuberculin positive. This is particularly so during adolescence and early adult life. It is therefore suggested that records of vaccination with B.C.G. and of tuberculin testing should be kept for *at least* ten years.

B.C.G. vaccination of hospital staff and medical and dental students should be recorded on Forms EC. 7A or EC. 8A or on a locally prepared form. If a member of the staff or a student transfers to another hospital or to another medical or dental school the record card should be sent there. Record cards should normally be retained by the hospital or school for at least ten years.

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